

present invention is directed to a device for shaping a collapsed viscus with each inflatable section giving shape to the collapsed viscus by acquiring its distended form when the section is inflated. Claims 2, 14 and 20 have been amended in a similar fashion as discussed below. No new issues are presented in this Amendment. Applicant explicitly reserves the right to pursue the subject matter of the cancelled claims in a continuing application.

The Examiner has previously rejected claims 1-20 as being clearly anticipated by the teachings of U.S. Patent No. 4,600,015 to Evans et al. (hereinafter "the Evans patent"). The Examiner's rejection of previous claims 2-5, 10-17 and 20 is respectfully traversed for the following reasons.

Turning first to method claims 14-17, the method of the present invention is to use the tool for "manipulating" a lumen during a surgical or diagnostic procedure. The procedure utilizes the device of the present invention by inserting a body member having a plurality of axially spaced independently inflatable sections into the lumen wherein each inflatable section is axially fixed relative to the remainder of the inflatable sections on the body member and selectively inflating independent sections of the body member to manipulate the lumen. Note that the title of the present invention is an inflatable intraluminal molding device. As described in the Background of the Invention, it is an object of the present invention to provide an inflatable intraluminal molding device for positioning, isolation or identification of the hollow viscus for use internally of the hollow viscus "to give shape to the collapsed viscus by acquiring its distended form." Claim 14 has been amended accordingly. *intended use*

The Evans patent teaches a patient monitoring apparatus and method. The device of the Evans patent can include positioning balloons 55 and 65 for positioning the device in the oesophagus. Additionally, it includes provoking balloons 52 and 62 which are used to provoke

contractions of the oesophagus. Finally, sensing balloons 51 or 61 can be provided for patient monitoring. None of the balloons in any of the embodiments of the Evans patent can be thought of as fairly teaching or suggesting manipulation of the lumen within the ordinary meaning of the term. Certainly none of these will shape a collapsed lumen as set forth in amended claim 14.

Again, the balloons 55 and 65 at the distal end of the various embodiments are used for positioning of the device, not to manipulate a lumen. Provoking balloons 51 and 61 are utilized to generate contractions of the oesophagus, but do not manipulate the lumen within the ordinary meaning of the term, or give shape to the collapsed lumen as further clarified in claim 14. The sensing balloons 52 and 62 also have no manipulating function. As a final point, it should be noted that claim 14 requires selectively inflating independent sections of the body member to manipulate the lumen requiring more than one section of the body member for performing manipulation on the lumen. As discussed above, the device in the Evans patent does not teach a single section for manipulating a collapsed lumen and, further, would not teach a plurality of independent sections, each of which manipulate the lumen. In summary, there is no teaching or suggestion of a method of manipulating a collapsed lumen to which claims 14-17 are clearly directed.

Claims 15 and 16 each depend from claim 14 and further define at least one tube provided between adjacent inflatable lumen manipulating sections and further comprising the step of either supplying a medium through the tube to the lumen between the inflatable sections or providing suction to the lumen through the tube between the inflated sections. This is an important aspect of the present invention which allows suction or application of fluid or a medium between inflated sections for selectively working on a portion of the lumen.

Dependent claim 2 has been rewritten in independent form and is directed toward a device having the elongated member with a plurality of independently inflatable sections which shape the collapsed lumen as discussed above and further defining that the body member is a single sleeve adapted to fit over an existing intraluminal tool. This is illustrated in Fig. 1 in which sleeve 12 is adapted to fit around an existing suction tube and scope member 20 allowing the present invention to be easily utilized with, and compliment, existing equipment. There is no teaching or suggestion in the Evans patent of having the body of the device be formed as a sleeve which can fit around an existing device. All of the devices of the Evans patent are integral devices not intended to slide over existing devices. Consequently, the subject matter of claim 2 is not taught or suggested by the teachings of the Evans patent.

Claim 4 depends from claim 1 and further defines at least four adjacent inflatable sections which is not addressed in the prior art of record.

Claim 12 depends from claim 1 and further defines that the inflatable sections are adapted to conform to specific anatomical structures. This aspect of the present invention is illustrated with a gastrointestinal molding device of the present invention where a segment conforms to a portion of the stomach. As discussed above, the Evans patent is not a molding or manipulating device and none of the individual inflatable sections conforms to specific anatomical structures. The device of the Evans patent is not intended to be used in that manner and this limitation is not taught or suggested. Claim 12 is believed to further distinguish the present invention from the applied prior art.

Claim 20 has been rewritten in independent form and is also directed to an intraluminal surgical and diagnostic device and defines that the body member has a series of independently inflatable/deflatable balloon sections each of which can shape the collapsed lumen

as discussed above, with at least one inflating/deflating line extending to each balloon section.

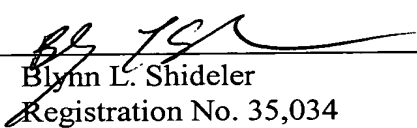
Claim 20 further defines a suction tube extending from a leading end of the body member to a distal end of the body member and defines at least one tube extending from between adjacent balloon sections to the distal end of the body member. As discussed above, the Evans patent does disclose a structure with a plurality of shaping or molding balloons for use in collapsed lumens.

Favorable action on all of the claims is respectfully requested for all of the reasons set forth herein.

Respectfully submitted,

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MARKED -UP VERSIONS OF REWRITTEN CLAIMS

1. (Once Amended) An intraluminal device for shaping a collapsed viscus,
the device comprising:

an elongated body member, the elongated body member having [a plurality of]
at least three independent inflatable sections along the length of the body member, wherein the
independent inflatable sections are axially spaced along the body member and each inflatable
section is axially fixed relative to the remainder of the axially spaced inflatable sections, and
wherein each inflatable section is designed to give shape to a collapsed viscus by acquiring its
distended form when the inflated section is in the inflated condition;

at least one tube positioned between adjacent inflatable sections, wherein each
adjacent inflatable section extends around the entire circumference of the body, and wherein the
tube extends from a peripheral portion of the device between adjacent inflatable sections to a
distal end of the body member, wherein the tube is adapted to be selectively attached to a section
source or a fluid supply source; and

means for independently inflating each individual inflatable section to give shape
to a collapsed viscus by acquiring its distended form when the inflated section is in the inflated
condition.

2. (Once Amended) An intraluminal [The] device for shaping a collapsed
viscus [of claim 1] comprising:

an elongated body member, the elongated body member having a plurality of
independent inflatable sections along the length of the body member, wherein the plurality of
independent inflatable sections are axially spaced along the body member and each inflatable

section is axially fixed relative to the remainder of the axially spaced inflatable sections, and
wherein the body member is a single sleeve which is adapted to fit over an existing intraluminal
tool; and

means for independently inflating each individual inflatable section to give shape
to the collapsed viscus by acquiring its distended form when the inflated section is in the inflated
condition.

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4. (Once Amended) The device of claim [3] 1 further including at least four
of the [one tube positioned between] adjacent inflatable sections and [extending to a distal end
of the body member,] wherein a plurality of the tubes are provided with each tube is adapted to
be selectively attached to a suction [source] hose or a fluid supply source.

check figure 21
8. (Once Amended) The device of claim [7] 6 further including at least one
optical scope positioned between adjacent inflatable sections and extending to a distal end of the
body member.

14. (Once Amended) A method of manipulating a collapsed hollow lumen R
during surgical or diagnostic procedures comprising the steps of :

inserting a body member having [a plurality of] at least three axially
spaced independent inflatable sections into the lumen; and

selectively inflating independent sections of the body member [to manipulate]
giving shape to the collapsed lumen by acquiring its distended form when the section is in the
inflated condition whereby the inflated balloon section manipulates the lumen.

20. (Amended) An intraluminal and surgical diagnostic [The] device for shaping a collapsed viscus [of claim 19 further including] comprising:

an intraluminal body member having a series of axially spaced independently inflatable/deflatable balloon sections along the length of the body member wherein each balloon section is axially fixed on the body member relative to the remainder of the axially spaced balloon sections, and wherein each balloon section will give shape to the collapsed viscus by acquiring its distended form when the balloon section is in the inflated condition whereby the inflated balloon section manipulates the hollow viscus;

a suction tube extending from a leading end of the body member to a distal end of the body member; and

at least one tube extending from a peripheral portion of the device between adjacent balloon sections to the distal end of the body member, wherein each adjacent balloon section extends around the entire circumference of the body.

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still